

EPA Registration File No. 9402-10 Vol. 2

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 9402-10

Send to SIG: check box ☐

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label

☒ Other: file letter in Jacket

~~Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).~~

Reviewer's Name: Whitaker

Phone: 308-2003 Division: AD

Date: 12/12/06

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager								
PRODUCT REVIEWER <i>R Whitaker</i>						RMB <u>II</u>		TEAM <u>34</u>	
Description of Action:						EPA File Symbol/Reg No. <i>9402-10</i>			
Decision No. <i>371154</i>			Submission No. <i>799651</i>			Fee for Service Action Code:			
FOIPA Action Code: <i>362</i>			Non-FOIPA Action Code:			PRIA FEE AMOUNT:			
			MONTH		DAY		YEAR		
APPLICATION DATE			SEPTEMBER		<i>26</i>		2006		
EPA PIN DATE			OCTOBER <i>Sept</i>		<i>29</i>		2006		
REVIEWER ASSIGNED DATE			OCTOBER		<i>04</i>		2006		
DATE DUE FROM SCIENCE							2006		
DATE DUE TO PM							200_		
DATE DUE OUT OF AGENCY									
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure		
COMMENTS:									
ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS									
B	For Arctic Slope Contract Only								
Contract No.: 0030			ARCTIC SLOPE/MANAGER						
Final Task: Signature _____ (Total hrs)									
C	Reviewer=s Comments:								
DATE FEE PAID:				RESPONSE CODE: <i>1355</i> RESPONSE DATE: <i>12/12/06</i>					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 12, 2006

Christina M. Swick
Lewis & Harrison Consultant
Agent for
Kimberly-Clark Global Sales, Inc.
122 C Street, N.W., Suite 740
Washington, DC 20001

Subject: **Kleenex® Brand Anti-Viral Tissue**
Confirmation of Request to Withdraw Application
EPA Registration Number 9402-10
Application: October 24, 2006
Receipt Date: October 24, 2006

Dear Ms. Swick:

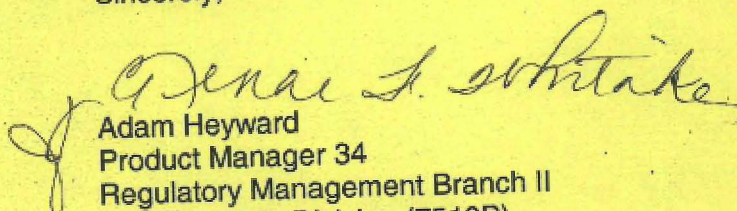
This letter is to confirm that the Agency has received your request to voluntarily withdraw the above application.

General Comment:

Any future submission related to this submission must be submitted as a new registration application.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email address at heyward.adam@epa.gov, or Renae Whitaker telephone at (703) 308-7003 or email address at whitaker.renae@epa.gov.

Sincerely,


Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

October 24, 2006

HAND DELIVERED

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

ATTN: Adam Heyward
Product Manager, Team 34

SUBJECT: Kimberly-Clark Global Sales, Inc.
Kleenex® Brand Anti-Viral Tissue (EPA Reg. No. 9402-10)
Request to Withdraw Application for Formulation Amendment

Dear Mr. Heyward:

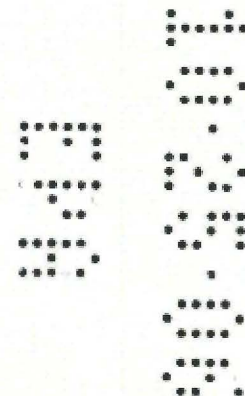
On behalf of Kimberly-Clark Global Sales, Inc., I would like to officially withdraw the formulation amendment application for Kleenex® Brand Anti-Viral Tissue dated September 26, 2006.

If you have any questions, please contact me at (202) 393-3903 ext. 16 or by e-mail me at cswick@lewisharrison.com

Sincerely,



Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

11/01/06

DP BARCODE: D332995

MRID : None

SUBJECT: Kleenex[®] Brand Tissue Anti-Viral

REG. NO. OR FILE SYMBOL: 9402-10

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Citric Acid (021801); Sodium Lauryl Sulfate (079011)

CAS Number: (77-92-9), (151-21-3)

TEST LAB: N/A

SUBMITTER: Kimberly-Clark Global Sales, Inc.

GUIDELINE: None

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón ORGANIZATION: AD

APPROVER: Karen P. Hicks APPROVED DATE: 11/14/06

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

11/01/06

TO: Adam Heyward / Renae Whitaker
PM Team 34
FROM: Juan F. Negrón, Chemist *JFN*
Product Science Branch, CT Team
Antimicrobial Division (7510P)
THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C) *KPH*
THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510C)

APPLICANT: Kimberly-Clark Global Sales, Inc.
Action code: 362
Due date: 12/28/06

Product Formulation
Active Ingredient(s)

	% by wt.
Citric Acid	7.51
Sodium Lauryl Sulfate	2.02

BACKGROUND:

The registrant, Kimberly-Clark Global Sales, Inc., is submitting the basic formulation and two alternate formulations. The integrated end-use product, Kleenex[®] Brand Tissue Anti-Viral, kills Cold & Flu viruses.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
 - Letters, dated 09/26/06, & 10/24/06.
 - A label, dated 05/25/04.
 - Confidential Statements of formula (CSFs), dated 09/26/06 (EPA Form 8570-4), for the basic formulation and alternate (A & B) formulations.
 - Application for Pesticide, dated 09/26/06, EPA Form 8570-1.
2. The registrant withdraws the amendment application (see letter dated 10/24/06).

CONCLUSION:

The submission was not reviewed because the registrant has withdrawn the application.

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

September 26, 2006

HAND DELIVERED

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

ATTN: Adam Heyward
Product Manager, Team 34

SUBJECT: Kimberly-Clark Global Sales, Inc.
Kleenex[®] Brand Anti-Viral Tissue (EPA Reg. No. 9402-10)
Formulation Amendment

Dear Mr. Heyward:

On behalf of Kimberly-Clark Global Sales, Inc., I am submitting a formulation amendment for Kleenex[®] Brand Anti-Viral Tissue. The purpose of this amendment is to add additional sources for the active ingredients citric acid and sodium lauryl sulfate. Please note that these additional sources are identical in composition to the current sources of citric acid and sodium lauryl sulfate.

Enclosed please find the following documents in support of this amendment:

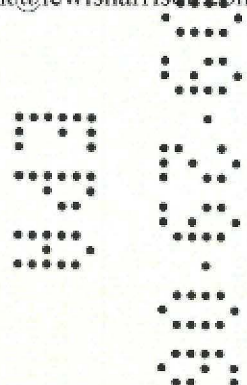
1. Application for Pesticide Amendment;
2. Confidential Statement of Formula (CSF) for Basic Formulation;
3. CSF for Alternate Formulation A; and,
4. CSF for Alternate Formulation B.

Insofar as Lewis & Harrison serves as the "Company Contact" and "Company Agent" for Kimberly-Clark Global Sales, Inc., please relay all correspondence regarding this notification directly to us. If you have any questions, please contact me at (202) 393-3903 ext. 16 or by e-mail me at cswick@lewisharrison.com

Sincerely,

Christina M. Swick

Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.



**EPA**

United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☒ **Amendment**
☐ **Other:**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number
 9402-10

2. EPA Product Manager
 Adam Heyward

3. Proposed Classification

4. Company/Product (Name)
 Kleenex® Brand Anti-Viral Tissue

PM#
 Team 34

☒ None ☐ Restricted

5. Name and Address of Applicant (Include ZIP Code)
 Kimberly-Clark Global Sales, Inc.
 2100 Winchester Road
 Neenah, WI 54956

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

PLEASE DIRECT ALL CORRESPONDENCE TO
"CONTACT POINT" LISTED BELOW

☐ Check if this is a new address

Section - II

☒ Amendment - Explain below.

☐ Final printed labels in response to Agency letter dated _____

☐ Resubmission in response to Agency letter dated _____

☐ "Me Too" Application

☐ Notification - Explain below.

☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

APPLICATION FOR FORMULATION AMENDMENT (see cover letter for details)**Section - III**

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes*
☐ No

Unit Packaging

☐ Yes
☐ No

Water Soluble Packaging

☐ Yes
☐ No

2. Type of Container

☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify)

***Certification must
 be submitted**

If "Yes" No. per
 Unit Packaging wgt. container

If "Yes" No. per
 Package wgt. container

3. Location of Net Contents Information
☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

☐ On Label
☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product

☐ Lithograph
☐ Paper glued
☐ Stenciled

☐ Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name: Christina M. Swick, Lewis and Harrison, LLC
 122 C St., NW Suite 740 Washington, DC 20001

Title:
 Agent for Kimberly-Clark Global Sales, Inc.

Telephone No. (Include Area Code): (202) 393-3903 x16

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application
 Received
 (Stamped)

2. Signature

Christina M. Swick

3. Title:

Agent for Kimberly-Clark Global Sales, Inc.

4. Typed Name

Christina M. Swick, Lewis & Harrison LLC

5. Date

September 26, 2006



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 4, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CHRISTINA M. SWICK, FOR LEWIS & HARRISON, AGENT
KIMBERLY-CLARK GLOBAL SALES, INC.
122 C ST., NW, SUITE 740
WASHINGTON, D.C. 20001

PRODUCT NAME: KLEENEX BRAND ANTI-VIRAL TISSUE
COMPANY NAME: KIMBERLY-CLARK GLOBAL SALES, INC.
EPA FILE SYMBOL: 9402-10
EPA RECEIPT DATE: 09/29/06

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at (703) 308-6422.

Sincerely,

A handwritten signature in cursive script, appearing to read "Julie", is positioned above the typed name and title.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{799651?~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: ____

for Division

- ☒ AD
- ☐ BPPD
- ☐ RD

Risk Mgr. 34

Receipt No.

S-

799651

EPA File Symbol/Reg. No.

9402-10

Pin-Punch Date:

9/29/2006

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

Reviewer: Jenkins/Fuller Date: 10-2-06

Remarks:

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 9402-10

Send to SIG: check box

This material is:

- ☒ New stamped-accepted label
☒ New CSF
☒ Notification
☐ Final Printed Label
Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Aster L. Kahn

Phone: 703 347 8737 Division: AD

Date: 10/16/06

RISK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II

A	Completed by Product Manager						
PRODUCT REVIEWER <i>Aster Graham</i>					RMB <u>II</u> TEAM <u>34</u>		
Description of Action:					EPA File Symbol/Reg No. <i>9402-10</i>		
Decision No. <i>371051</i>		Submission No. <i>799838</i>		Fee for Service Action Code:			
FQPA Action Code: <i>332</i>		Non-FQPA Action Code:		PRIA FEE AMOUNT:			
		MONTH		DAY		YEAR	
APPLICATION DATE		SEPTEMEBR		<i>26</i>		2006	
EPA PIN DATE		SEPTEMEBR		<i>28</i>		2006	
REVIEWER ASSIGNED DATE		SEPTEMEBR		<i>29</i>		2006	
DATE DUE FROM SCIENCE						2006	
DATE DUE TO PM		<i>Oct</i>		<i>15</i>		200_	
DATE DUE OUT OF AGENCY							
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure
COMMENTS: <div style="text-align: right; margin-top: 20px;"> NOTIFICATION Date Reviewed: <i>10-16-06</i> Reviewed By: <i>AGH</i> </div>							
ATTACHMENTS: €-LABELING €-CSF(S) €-DATA €-OTHERS							
B	For Arctic Slope Contract Only						
	Contract No.: 0030		ARCTIC SLOPE/MANAGER				
	Final Task: Signature <i>[Signature]</i>				<u>1.5</u> (Total hrs)		
C	Reviewer=s Comments:						
DATE FEE PAID:				RESPONSE CODE: <i>1155</i>		RESPONSE DATE: <i>10/16/06</i>	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

October 16, 2006

Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.
122 C St. NW Ste. 740
Washington, D.C. 20001

Subject: Kleenex Brand Anti-Virul Tissue
EPA Registration No.: 9402-10
Application Date: September 26, 2006
Receipt Date: September 28, 2006

Dear Ms. Swick,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Add additional sources for the active ingredients.

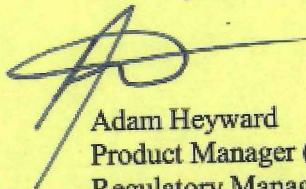
General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703)-308-6422.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
YMBOL	7510P						
JRNAME	Graham						
ATE	10/16/06						

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001

telephone 202.393.3903
fax 202.393.3906

September 26, 2006

HAND DELIVERED

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

ATTN: Adam Heyward
Product Manager, Team 34

SUBJECT: Kimberly-Clark Global Sales, Inc.
Kleenex® Brand Anti-Viral Tissue (EPA Reg. No. 9402-10)
Notification of Change in Source of Active Ingredients per PR Notice 98-10

Dear Mr. Heyward:

On behalf of Kimberly-Clark Global Sales, Inc., I am submitting a notification for Kleenex® Brand Anti-Viral Tissue. The purpose of this notification is to add additional sources for the active ingredients citric acid and sodium lauryl sulfate.

Enclosed please find the following documents in support of this notification:

1. Application for Pesticide Notification (OPP ID No. 265394), which includes a signed statement certifying compliance with PR Notice 98-10;
2. Confidential Statement of Formula (CSF) for Basic Formulation;
3. CSF for Alternate Formulation A; and,
4. CSF for Alternate Formulation B.

Insofar as Lewis & Harrison serves as the "Company Contact" and "Company Agent" for Kimberly-Clark Global Sales, Inc., please relay all correspondence regarding this notification directly to us. If you have any questions, please contact me at (202) 393-3903 ext. 16 or by e-mail me at cswick@lewisharrison.com

Sincerely,

Christina M. Swick

Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.

22

**EPA**

United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other: Notification**

OPP Identifier Number

265394

Application for Pesticide - Section I

1. Company/Product Number 9402-10	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Kleenex Brand Anti-Viral Tissue	PM# Team 34	
5. Name and Address of Applicant (include ZIP Code) Kimberly-Clark Global Sales, Inc. 2100 Winchester Road Neenah, WI 54956 <u>PLEASE DIRECT ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

- ☐ Amendment - Explain below. ☐ Final printed labels in response to Agency letter dated _____
☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
☒ Notification - Explain below. ☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**Notification to Change Source of Active Ingredients****Notification of in Accordance With PR Notice 98-10**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Christina M. SwickDate: 9/26/06**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)					
Name: Christina M. Swick, Lewis and Harrison 122 C St., NW Suite 740, Washington, DC 20001		Title: Agent for Kimberly-Clark Global Sales, Inc.		Telephone No. (Include Area Code): (202) 398-3903 x16	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.				6. Date Application Received (Stamped)	
2. Signature <u>Christina M. Swick</u>		3. Title: Agent for Kimberly-Clark Global Sales, Inc			
4. Typed Name Christina M. Swick, Lewis & Harrison LLC		5. Date September 26, 2006			

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II
For PRIA Submissions

A	Completed by Product Manager							
PRODUCT REVIEWER: RENAE WHITAKER					RMB <u>II</u> TEAM <u>34</u>			
Description of Action: MINOR AMENDMENT					EPA File Symbol/Reg No. 9402-10			
Decision No. <u>570/45</u>		Submission No. <u>798396</u>		Fee for Service Action Code: _____				
FQPA Action Code: <u>362</u>		Non-FQPA Action Code: _____		Fee for Service Fee: \$ _____				
	MONTH	DAY	YEAR					
APPLICATION DATE	AUGUST	15	2 0 0 6					
EPA PIN DATE	AUGUST	16	2 0 0 6					
REVIEWER ASSIGNED DATE	AUGUST	24	2 0 0 6					
DATE DUE FROM SCIENCE	-----	-----	2 0 0 6					
DATE DUE TO PM	OCTOBER	10	2 0 0 6					
DATE DUE OUT OF AGENCY	NOVEMBER	15	2 0 0 6					
Type of Data:	PSB Product Chemistry X	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure	
COMMENTS: NOTE TO ARCTIC SLOPE - PLEASE COMPLETE <u>PART B</u> OF FORM.								
ATTACHMENTS: •-LABELING •-CSF(S) •-DATA •-OTHERS								
B	For Arctic Slope Contract Only							
Contractor: Arctic Slope				Contract No.: EP-W-05-052		ARCTIC SLOPE/MANAGER		
Draft Task: Signature _____ _____ (Est. hrs)				Final Task: Signature _____ _____ (Total hrs)				
C	Reviewer's Comments:							
DATE FEE PAID:				RESPONSE CODE: <u>1130</u> RESPONSE DATE: <u>10/24/06</u>				



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 20, 2006

Christina M. Swick
Lewis & Harrison, LLC, Agent for
Kimberly-Clark Global Sales, Inc.
122 C Street, N.W. Suite 740
Washington, Dc 20001

Subject: **Kleenex® Brand Anti-Viral Tissue**
EPA Registration No. 9402-10
Application Date: August 15, 2006
Receipt Date: August 16, 2006

Dear Ms. Swick:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is unacceptable for the following reasons.

Proposed Amendment

- Alternate Confidential Statement of Formulas(CSFs) (see alternate CSFs A & B dated 08/15/06)

General Comments:

1. The CSFs and label must have the same nominal.
2. The calculation shows that the active ingredient (AI), citric acid, is [REDACTED]. The CSF shows 7.51%. the label claims 7.51%.
3. The Agency suggested representing a ratio value on the CSF form. The ratio value will allow a variety of batch productions by using [REDACTED] on box 17 of the CSF. Therefore, column 13a must be the same value as column 13b.

Other Comments:

For further detail refer to the enclosed PSB Product Chemistry review dated September 25, 2006.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker by telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure: [Product Chemistry Review]

34 *Inert ingredient information may be entitled to confidential treatment*

Product ingredient source information may be entitled to confidential treatment

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

August 15, 2005

HAND DELIVERED

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

ATTN: Adam Heyward
Product Manager, Team 34

SUBJECT: Kimberly-Clark Global Sales, Inc.
Kleenex® Brand Anti-Viral Tissue (EPA Reg. No. 9402-10)
Minor Formulation Amendment per PR Notice 98-10

Dear Mr. Heyward:

On behalf of Kimberly-Clark Global Sales, Inc., I am submitting a minor formulation amendment for Kleenex® Brand Anti-Viral Tissue. The purpose of this amendment is to create alternate formulations A and B. The only difference between these formulations and the currently approved basic formulation involves the inert ingredient.

In alternate formulation A, the supplier of [REDACTED] has been changed from [REDACTED] to [REDACTED]. In alternate formulation B, [REDACTED] is being replaced with another [REDACTED]. Please note the compositional information for these inert ingredients was submitted by [REDACTED] to Nancy Whyte in a letter dated [REDACTED].

Enclosed please find the following documents in support of this amendment:

1. Application for Pesticide Amendment;
2. Two (2) copies of the CSF for Alternate Formulation A; and,
3. Two (2) copies of the CSF for Alternate Formulation B.

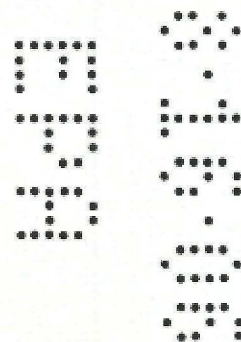
Insofar as Lewis & Harrison serves as the "Company Contact" and "Company Agent" for Kimberly-Clark Global Sales, Inc., please relay all correspondence regarding this notification directly to us. If you have any questions, please contact me at (202) 393-3903 ext. 16 or by e-mail me at cswick@lewisharrison.com

Sincerely,

Christina M. Swick

Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.

cc: Michael Caringello (Kimberly-Clark Global Sales, Inc.)



**EPA**

United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☒ **Amendment**
☐ **Other:**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 9402-10	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Kleenex® Brand Anti-Viral Tissue	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) Kimberly-Clark Global Sales, Inc. 2100 Winchester Road Neenah, WI 54956 <u>PLEASE DIRECT ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- ☒ Amendment – Explain below. ☐ Final printed labels in response to Agency letter dated _____
☐ Resubmission in response to Agency letter dated _____ ☐ "Me Too" Application
☐ Notification - Explain below. ☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**APPLICATION FOR MINOR FORMULATION AMENDMENT (see cover letter for details)****Section - III****1. Material This Product Will Be Packaged In:**

Child-Resistant Packaging

- ☐ Yes*
☐ No

Unit Packaging

- ☐ Yes
☐ No

Water Soluble Packaging

- ☐ Yes
☐ No

2. Type of Container

- ☐ Metal
☐ Plastic
☐ Glass
☐ Paper
☐ Other (Specify)

***Certification must be submitted**

If "Yes" No. per
 Unit Packaging wgt. container

If "Yes" No. per
 Package wgt. container

3. Location of Net Contents Information
☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions

- ☐ On Label
☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product

- ☐ Lithograph ☐ Other _____
☐ Paper glued
☐ Stenciled

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name: **Christina M. Swick, Lewis and Harrison, LLC**
122 C St., NW Suite 740 Washington, DC 20001

Title: _____
Agent for Kimberly-Clark Global Sales, Inc.

Telephone No. (include Area Code): **(202) 393-3903 x16**

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature

Christina M. Swick

3. Title:

Agent for Kimberly-Clark Global Sales, Inc.

4. Typed Name

Christina M. Swick, Lewis & Harrison LLC

5. Date

August 15, 2006

6. Date Application Received
(Stamped)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

09/25/06

DP BARCODE: D332055

MRID : None

SUBJECT: Kleenex[®] Brand Tissue Anti-Viral

REG. NO. OR FILE SYMBOL: 9402-10

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use ☐ OR End-use Product ☒

INGREDIENTS (PC Codes) Citric Acid (021801); Sodium Lauryl Sulfate (079011)

CAS Number: (77-92-9), (151-21-3)

TEST LAB: N/A

SUBMITTER: Kimberly-Clark Global Sales, Inc.

GUIDELINE: None

COMMODITIES: Formulation

REVIEWER: Juan F. Negrón ORGANIZATION: AD

APPROVER: Karen P. Hicks APPROVED DATE: 9/26/06

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

09/25/06

TO: Adam Heyward / Renae Whitaker
PM Team 34
FROM: Juan F. Negrón, Chemist
Product Science Branch, CT Team
Antimicrobial Division (7510P)
THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobial Division (7510C)
THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobial Division (7510C)
APPLICANT: Kimberly-Clark Global Sales, Inc.
Action code: 362
Due date: 11/14/06

A handwritten signature in blue ink, likely belonging to Karen P. Hicks, is written over the "THRU:" line for Karen P. Hicks.

Product Formulation
Active Ingredient(s)

	% by wt.
Citric Acid	7.51
Sodium Lauryl Sulfate	2.02

BACKGROUND:

The registrant, Kimberly-Clark Global Sales, Inc., is submitting two alternate formulations. The integrated end-use product, Kleenex[®] Brand Tissue Anti-Viral, kills Cold & Flu viruses.

FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
 - A letter, dated 08/15/05.
 - A label, dated 05/25/04.
 - Confidential Statements of formula (CSFs), dated 08/15/06, EPA Form 8570-4.
2. The CSFs, dated 08/15/06, for the alternate (A & B) formulations are revised.
3. The CSFs and the label do not have the same nominal.
4. The calculation shows that the active ingredient (AI), citric acid, is [REDACTED]. The CSF shows 7.51%. The label claim 7.51%.
5. The AI, Sodium Lauryl Sulfate (SLS), nominal calculation shows [REDACTED] with a purity of [REDACTED] (see column 10). The CSF does not show the nominal for the percentage by weight and the certified limits. Instead, the CSF shows the percentage of material. The percentage of material does not satisfy the EPA Standard Certified Limits. The label claim 2.02%.
6. None of the components of the formula on the CSF meets EPA Standard Certified Limits.
7. The registrant is using a rate, lbs/ft², in column 13a (amount).

RECOMMENDATIONS:

1. The CSFs and the label must have the same nominal.
2. All certified limits must meet the EPA Standard Certified Limits unless the registrant claims wider certified limits. The registrant must submit a justification for wider certified limits for each component.
3. The Agency suggested representing a ratio value on the CSF form. The ratio value will allow a variety of batch productions by using [REDACTED] on box 17 of the CSF. Therefore, column 13a should be the same value as column 13b.

CONCLUSION:

The CSFs, dated 08/15/06, are not acceptable. The registrant must comply with the requirements, recommendations and findings listed above.

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 9402-10

Send to SIG: check box ☒

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☒ Notification
- ☐ Final Printed Label
- ☐ Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Aster Gahn

Phone: 703 347 8137 Division: AD

Date: Sept 15, 2006

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branch II
For PRIA Submissions

A	Completed by Product Manager						
PRODUCT REVIEWER: ASTER GRAHN					RMB <u>II</u> TEAM <u>34</u>		
Description of Action: NOTICATION					EPA File Symbol/Reg No. 9402-10		
Decision No. <u>370128</u>		Submission No. <u>798356</u>		Fee for Service Action Code: _____			
FQPA Action Code: <u>332</u>		Non-FQPA Action Code: _____		Fee for Service Fee: \$ _____			
		MONTH	DAY	YEAR			
APPLICATION DATE		AUGUST	15	2006			
EPA PIN DATE		AUGUST	16	2006			
REVIEWER ASSIGNED DATE		AUGUST	24	2006			
DATE DUE FROM SCIENCE		-----	-----	2006			
DATE DUE TO PM		SEPTEMBER	10	2006			
DATE DUE OUT OF AGENCY		SEPTEMBER	16	2006			
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure
COMMENTS: NOTE TO ARCTIC SLOPE - PLEASE COMPLETE <u>PART B</u> OF FORM.							
ATTACHMENTS: •-LABELING •-CSF(S) •-DATA •-OTHERS							
B	For Arctic Slope Contract Only						
Contractor: Arctic Slope				Contract No.: 0332		ARCTIC SLOPE/MANAGER	
Draft Task: Signature _____ (Est. hrs)				Final Task: Signature <u>[Signature]</u> <u>15</u> (Total hrs)			
C	Reviewer's Comments:						
DATE FEE PAID:				RESPONSE CODE: <u>1155</u> RESPONSE DATE: <u>9/15/06</u>			

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

September 16, 2006

Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.
Lewis & Harrison, LLC
122 C. St. NW Ste. 740
Washington, DC 20001

Subject: Kleenex Brand Anti-Viral Tissue
EPA Registration No.: 9402-10
Application Date: August 15, 2006
Receipt Date: August 16, 2006

Dear Ms. Swick,

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- Addition of the marketing language "3 Pack Bundle Pack" and "Take care. Be Prepared."

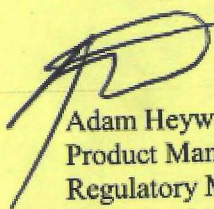
General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES							
YMBOL	7510P						
JRNAME	Graham						
ATE	9/16/06						

34

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W., Suite 740
Washington, D.C. 20001
telephone 202.393.3903
fax 202.393.3906

August 15, 2005

HAND DELIVERED

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington VA 22202

ATTN: Adam Heyward
Product Manager, Team 34

SUBJECT: Kimberly-Clark Global Sales, Inc.
Kleenex® Brand Anti-Viral Tissue (EPA Reg. No. 9402-10)
Notification of Optional Marketing Language per PR Notice 98-10

Dear Mr. Heyward:

On behalf of Kimberly-Clark Global Sales, Inc., I am submitting a notification for Kleenex® Brand Anti-Viral Tissue. The purpose of this notification is to add optional marketing language to the product label. Specifically we wish to add the optional marketing statements, "3 Pack Bundle Pack®" and "take care. be prepared."

Enclosed please find the following documents in support of this notification:

1. Application for Pesticide Notification (OPP ID No. 265394), which includes a signed statement certifying compliance with PR Notice 98-10, and;
2. One (1) copy of the labeling panels which contain the optional marketing language.

Insofar as Lewis & Harrison serves as the "Company Contact" and "Company Agent" for Kimberly-Clark Global Sales, Inc., please relay all correspondence regarding this notification directly to us. If you have any questions, please contact me at (202) 393-3903 ext. 16 or by e-mail me at cswick@lewisharrison.com

Sincerely,

Christina M. Swick

Christina M. Swick
Agent for Kimberly-Clark Global Sales, Inc.

cc: Michael Caringello (Kimberly-Clark Global Sales, Inc.)

35

**EPA**

United States
Environmental Protection Agency
Washington, DC 20460

- ☐ Registration
☐ Amendment
☒ Other: Notification

OPP Identifier Number
265394

Application for Pesticide - Section I

1. Company/Product Number 9402-10	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Kleenex Brand Anti-Viral Tissue	PM# Team 34	
5. Name and Address of Applicant (Include ZIP Code) Kimberly-Clark Global Sales, Inc. 2100 Winchester Road Neenah, WI 54956 <u>PLEASE DIRECT ALL CORRESPONDENCE TO</u> <u>"CONTACT POINT" LISTED BELOW</u> <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

- | | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below |

Explanation: Use additional page(s) if necessary. (For Section I and Section II.)**Notification to Add Optional Marketing Language****Notification of in Accordance With PR Notice 98-10**

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be the subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Signature: Christina M. SwickDate: 8/15/06**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
*Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Plastic	
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)

Name: Christina M. Swick, Lewis and Harrison 122 C St., NW Suite 740, Washington, DC 20001	Title: Agent for Kimberly-Clark Global Sales, Inc.	Telephone No. (Include Area Code): (202) 393-3903 x16
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <u>Christina M. Swick</u>	3. Title: Agent for Kimberly-Clark Global Sales, Inc.	
4. Typed Name Christina M. Swick, Lewis & Harrison LLC	5. Date August 15, 2006	



KLEENEX® Anti-Viral 3x112ct Bundle Label - MIU - TARGET HEALTH & WELLNESS

PROJECT: Kln TARGET HEALTH & WELLNESS PSRVL
DOCUMENT NAME: 061003 KlnTghW3x112
LAYERS: 5
PLACED ART:
PROGRAM: Adobe Illustrator CS(11)
PRODUCED: 06.30.06 jlb 4:00PM
FONTS: Helvetica (Regular, Bold, Black);
Stone Sans (Regular, Bold, Semibold);
Optima (Bold)

KC JOB NUMBER:
KC SPEC NUMBER: 00-00-000-0-00
CLIENT: Terry Wadell
MILL NAME:
DRAWING NUMBER:
REDUCED SIZE: 100%
SEPARATOR: OUTLOOK
PRINTER: OUTLOOK

APPROVED ART DATE:

STOCK CODE:

PREVIOUS JOB#:

REVISIONS: 07.11.06 jlb 11:10am; Changed the "Kills 99.9%" copy to be 5% smaller.

FOR PANTONE NUMBERS ONLY, DO NOT COLOR MATCH



PANTONE 151



PANTONE 286



PANTONE 186



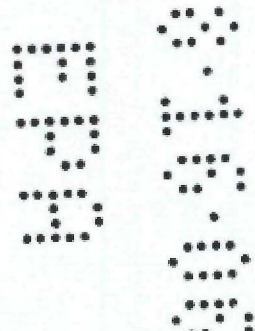
PANTONE 288



PANTONE 151



PANTONE 286



take care.
be prepared.

KILLS 99.9% OF COLD & FLU VIRUSES*

IN THE TISSUE WITHIN 15 MINUTES

*See back for anti-viral details.

Kleenex®

Anti-Viral*

**BRAND
TISSUE**

3 PACK BUNDLE PACK®

EACH 112 3-PLY TISSUES

8.4 x 8.2 in / 21.3 x 20.8 cm

TOTAL 336

Current

kcs-061303

07.10.06

